

HOUSE BILL No. 1276

DIGEST OF INTRODUCED BILL

Citations Affected: IC 25-26-13.

Synopsis: Dispensing without a prescription. Allows a pharmacist who meets certain requirements to furnish specified tobacco cessation products and immunization drugs or devices to individuals who are at least 18 years of age without a prescription or drug order. Provides that a third party contract or other agreement that restricts a pharmacist from practicing any legally allowed duty or action is void.

Effective: July 1, 2016.

Davisson

January 12, 2016, read first time and referred to Committee on Public Health.



Second Regular Session of the 119th General Assembly (2016)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2015 Regular Session of the General Assembly.

HOUSE BILL No. 1276

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

Be it enacted by the General Assembly of the State of Indiana:

1 SECTION 1. IC 25-26-13-25, AS AMENDED BY P.L.13-2013,
2 SECTION 69, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
3 JULY 1, 2016]: Sec. 25. (a) All original prescriptions, whether in
4 written or electronic format, shall be numbered and maintained in
5 numerical and chronological order, or in a manner approved by the
6 board and accessible for at least two (2) years in the pharmacy. A
7 prescription transmitted from a practitioner by means of
8 communication other than writing must immediately be reduced to
9 writing or recorded in an electronic format by the pharmacist. The files
10 shall be open for inspection to any member of the board or the board's
11 duly authorized agent or representative.

12 (b) A prescription may be electronically transmitted from the
13 practitioner by computer or another electronic device to a pharmacy
14 that is licensed under this article or any other state or territory. An
15 electronic data intermediary that is approved by the board:

16 (1) may transmit the prescription information between the
17 prescribing practitioner and the pharmacy;



(2) may archive copies of the electronic information related to the transmissions as necessary for auditing and security purposes; and
 (3) must maintain patient privacy and confidentiality of all archived information as required by applicable state and federal laws.

(c) Except as provided in subsection (d) **and section 34 of this chapter**, a prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may not be refilled without written, electronically transmitted, or oral authorization of a licensed practitioner.

(d) **Except as provided in section 34 of this chapter**, a prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may be refilled by a pharmacist one (1) time without the written, electronically transmitted, or oral authorization of a licensed practitioner if all of the following conditions are met:

(1) The pharmacist has made every reasonable effort to contact the original prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(2) The pharmacist believes that, under the circumstances, failure to provide a refill would be seriously detrimental to the patient's health.

(3) The original prescription authorized a refill but a refill would otherwise be invalid for either of the following reasons:

(A) All of the authorized refills have been dispensed.

(B) The prescription has expired under subsection (h).

(4) The prescription for which the patient requests the refill was:

(A) originally filled at the pharmacy where the request for a refill is received and the prescription has not been transferred for refills to another pharmacy at any time; or

(B) filled at or transferred to another location of the same pharmacy or its affiliate owned by the same parent corporation if the pharmacy filling the prescription has full access to prescription and patient profile information that is simultaneously and continuously updated on the parent corporation's information system.

(5) The drug is prescribed for continuous and uninterrupted use and the pharmacist determines that the drug is being taken properly in accordance with IC 25-26-16.

(6) The pharmacist shall document the following information regarding the refill:



- 1 (A) The information required for any refill dispensed under
- 2 subsection (e).
- 3 (B) The dates and times that the pharmacist attempted to
- 4 contact the prescribing practitioner or the practitioner's
- 5 designee for consultation and authorization of the prescription
- 6 refill.
- 7 (C) The fact that the pharmacist dispensed the refill without
- 8 the authorization of a licensed practitioner.
- 9 (7) The pharmacist notifies the original prescribing practitioner
- 10 of the refill and the reason for the refill by the practitioner's next
- 11 business day after the refill has been made by the pharmacist.
- 12 (8) Any pharmacist initiated refill under this subsection may not
- 13 be for more than the minimum amount necessary to supply the
- 14 patient through the prescribing practitioner's next business day.
- 15 However, a pharmacist may dispense a drug in an amount greater
- 16 than the minimum amount necessary to supply the patient through
- 17 the prescribing practitioner's next business day if:
- 18 (A) the drug is packaged in a form that requires the pharmacist
- 19 to dispense the drug in a quantity greater than the minimum
- 20 amount necessary to supply the patient through the prescribing
- 21 practitioner's next business day; or
- 22 (B) the pharmacist documents in the patient's record the
- 23 amount of the drug dispensed and a compelling reason for
- 24 dispensing the drug in a quantity greater than the minimum
- 25 amount necessary to supply the patient through the prescribing
- 26 practitioner's next business day.
- 27 (9) Not more than one (1) pharmacist initiated refill is dispensed
- 28 under this subsection for a single prescription.
- 29 (10) The drug prescribed is not a controlled substance.
- 30 A pharmacist may not refill a prescription under this subsection if the
- 31 practitioner has designated on the prescription form the words "No
- 32 Emergency Refill".
- 33 (e) When refilling a prescription, the refill record shall include:
- 34 (1) the date of the refill;
- 35 (2) the quantity dispensed if other than the original quantity; and
- 36 (3) the dispenser's identity on:
- 37 (A) the original prescription form; or
- 38 (B) another board approved, uniformly maintained, readily
- 39 retrievable record.
- 40 (f) The original prescription form or the other board approved
- 41 record described in subsection (e) must indicate by the number of the
- 42 original prescription the following information:



- (1) The name and dosage form of the drug.
- (2) The date of each refill.
- (3) The quantity dispensed.
- (4) The identity of the pharmacist who dispensed the refill.
- (5) The total number of refills for that prescription.

(g) This subsection does not apply:

- (1) unless a patient requests a prescription drug supply of more than thirty (30) days;
- (2) to the dispensing of a controlled substance (as defined in IC 35-48-1-9); or
- (3) if a prescriber indicates on the prescription that the quantity of the prescription may not be changed.

A pharmacist may dispense, upon request of the patient, personal or legal representative of the patient, or guardian of the patient, not more than a ninety (90) day supply of medication if the patient has completed an initial thirty (30) day supply of the drug therapy and the prescription, including any refills, allows a pharmacist to dispense at least a ninety (90) day supply of the medication. However, a pharmacist shall notify the prescriber of the change in the quantity filled and must comply with state and federal laws and regulations concerning the dispensing limitations concerning a prescription drug. The pharmacist shall inform the customer concerning whether the additional supply of the prescription will be covered under the patient's insurance, if applicable.

(h) A prescription is valid for not more than one (1) year after the original date of issue.

(i) A pharmacist may not knowingly dispense a prescription after the demise of the practitioner, unless in the pharmacist's professional judgment it is in the best interest of the patient's health.

(j) A pharmacist may not knowingly dispense a prescription after the demise of the patient.

(k) A pharmacist or a pharmacy shall not resell, reuse, or redistribute a medication that is returned to the pharmacy after being dispensed unless the medication:

- (1) was dispensed to an individual:
 - (A) residing in an institutional facility (as defined in 856 IAC 1-28.1-1(6));
 - (B) in a hospice program under IC 16-25; or
 - (C) in a county jail or department of correction facility;
- (2) was properly stored and securely maintained according to sound pharmacy practices;
- (3) is returned unopened and:



- 1 (A) was dispensed in the manufacturer's original:
- 2 (i) bulk, multiple dose container with an unbroken tamper
- 3 resistant seal; or
- 4 (ii) unit dose package; or
- 5 (B) was packaged by the dispensing pharmacy in a:
- 6 (i) multiple dose blister container; or
- 7 (ii) unit dose package;
- 8 (4) was dispensed by the same pharmacy as the pharmacy
- 9 accepting the return;
- 10 (5) is not expired; and
- 11 (6) is not a controlled substance (as defined in IC 35-48-1-9),
- 12 unless the pharmacy holds a Category II permit (as described in
- 13 section 17 of this chapter).
- 14 (l) A pharmacist or a pharmacy shall not resell, reuse, or redistribute
- 15 medical devices or medical supplies used for prescription drug therapy
- 16 that have been returned to the pharmacy after being dispensed unless
- 17 the medical devices or medical supplies:
- 18 (1) were dispensed to an individual in a county jail or department
- 19 of correction facility;
- 20 (2) are not expired; and
- 21 (3) are returned unopened and in the original sealed packaging.
- 22 (m) A pharmacist may use the pharmacist's professional judgment
- 23 as to whether to accept medication for return under this section.
- 24 (n) A pharmacist who violates subsection (d) commits a Class A
- 25 infraction.
- 26 SECTION 2. IC 25-26-13-34 IS ADDED TO THE INDIANA
- 27 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
- 28 [EFFECTIVE JULY 1, 2016]: **Sec. 34. (a) A pharmacist who meets**
- 29 **the requirements of this section and rules adopted by the board**
- 30 **may furnish the drugs or devices specified in this section to**
- 31 **individuals who are at least eighteen (18) years of age without a**
- 32 **prescription or drug order.**
- 33 **(b) Before July 1, 2017, the board shall adopt rules under**
- 34 **IC 4-22-2 to establish protocols for pharmacists and record**
- 35 **keeping requirements under this section.**
- 36 **(c) A pharmacist shall notify the individual's primary care**
- 37 **provider of any drugs or devices furnished under this section to the**
- 38 **individual, or enter the appropriate information in a patient record**
- 39 **system shared with the primary care provider. If the individual**
- 40 **does not have a primary care provider, the pharmacist shall**
- 41 **provide the individual with a written record of the drugs or devices**
- 42 **furnished under this section and advise the individual to consult a**



1 physician of the individual's choice.

2 (d) A pharmacist shall:

3 (1) receive consent from an individual who receives a drug or
4 device before the pharmacist may provide the individual the
5 drug or device under this section; and

6 (2) document each drug or device furnished under this
7 section, including a unique number assigned by the
8 pharmacist for record keeping purposes.

9 The consent and documentation concerning the drug or device
10 furnished to the individual must be documented, numbered, and
11 maintained in numerical and chronological order, or in a manner
12 approved by the board and accessible for a period of three (3)
13 years.

14 (e) A pharmacist may furnish tobacco cessation products,
15 including nicotine replacement and nonnicotine replacement drugs
16 and devices approved by the federal Food and Drug
17 Administration, for use by prescription if the following conditions
18 are met:

19 (1) The pharmacist is certified in smoking cessation therapy
20 by an organization that is:

21 (A) recognized by the board; and

22 (B) accredited by the Accreditation Council for Pharmacy
23 Education (ACPE).

24 (2) After the pharmacist has received certification under
25 subdivision (1), the pharmacist completes one (1) hour of
26 continuing education focused on smoking cessation therapy
27 biennially.

28 (f) Notwithstanding section 31.2 of this chapter, a pharmacist
29 may furnish the following immunizations:

30 (1) Immunizations listed in the federal Centers for Disease
31 Control and Prevention's recommended adult immunization
32 schedule.

33 (2) Immunizations recommended by the federal Centers for
34 Disease Control and Prevention's health information for
35 international travel.

36 (3) Immunizations administered by pharmacists under section
37 31.2(b)(1) through 31.2(b)(6) of this chapter.

38 (g) A pharmacist or pharmacist's designee shall provide
39 immunization data to the immunization data registry (IC 16-38-5)
40 in a manner prescribed by the state department of health unless:

41 (1) the individual receiving the immunization; or

42 (2) the legal guardian of the individual receiving the



1 immunization, if a legal guardian has been appointed;
2 has completed and filed with the pharmacist or pharmacist's
3 designee a written immunization data exemption form, as provided
4 in IC 16-38-5-2.

5 SECTION 3. IC 25-26-13-35 IS ADDED TO THE INDIANA
6 CODE AS A NEW SECTION TO READ AS FOLLOWS
7 [EFFECTIVE JULY 1, 2016]: **Sec. 35. (a) A third party contract or**
8 **other agreement may not restrict a pharmacist from practicing any**
9 **duties or actions allowed under this article.**

10 **(b) A third party contract provision or other agreement that**
11 **violates this section is void.**

